REMARKS

Applicants respectfully request entry of the Amendment and reconsideration of the claims. Claim 1 has been amended to specify that the administration should be done by intravenous injection and to correct an obvious typographical error. Support for the amendment to claim 1 can be found throughout the specification, including at page 23, lines 13-15 and page 52, lines 15-19. Claims 3 and 4 have been cancelled. Claim 6 has been amended to clarify the dosage. Applicants respectfully request reconsideration and withdrawal of the rejections under the judicial doctrine of obviousness-type double patenting, 35 U.S.C. § 112, second paragraph, and 35 U.S.C. § 103(a).

Obviousness-type Double Patenting Rejection

The Examiner rejects claims 1 and 3-6 as being allegedly unpatentable over claims 1-11 of U.S. Patent No. 6,586,414 under the judicial doctrine of nonstatutory obviousness-type double patenting. While not acquiescing to the rejection and in order to expedite prosecution, Applicants submit a terminal disclaimer to U.S. Patent No. 6,586,414 to obviate the obviousness-type double patenting rejection.

In view of the foregoing, Applicants respectfully request removal of the obviousness-type double patenting rejection.

35 U.S.C. § 112, second paragraph

The Examiner rejects claim 6 as allegedly being indefinite. Specifically, the Examiner stated that the recitation of "in a range" followed by a single 40 mg/kg dosage lacks clarity. The Examiner suggested that the recitation of "in a range of" should be deleted. Applicant has amended the claim accordingly.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 103(a)

The Examiner rejects claims 1 and 3-6 as allegedly being unpatentable over Skochii et al. Specifically, the Examiner states that the "therapeutically effective amount" recited in claim 1

"about 0.5 mg/kg to 50 mg/kg per day of the mammal's body weight" overlaps with, or encompasses those recited in the reference. Applicants respectfully traverse.

To establish a *prima facie* case of obviousness, three criteria must be met--a suggestion or motivation to combine references, a reasonable expectation of success, and the prior art reference teaches or suggests all the claim limitations. MPEP §2143; *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). Applicants respectfully submit that the Skochii et al. reference does not provide a reasonable expectation of success nor discloses or suggests all of the claim limitations.

Applicants have previously provided a translation of Skochii et al. Applicants have had the Skochii et al. article re-translated by an expert translator (Andrey Bondarenko of Richmond, BC, Canada) and thereby providing a new translation of Skochii et al. herein. The previous translation of Skochii et al. was incorrect, in that a semi-colon not found in the original was inserted into the translated paper. This punctuation can be seen at p. 2, third full paragraph, last two lines. Thus "2 g of pyridoxal phosphate intramuscular injection once a day; 0.5 g of glutamic acid perorally or 10 ml of 1% solution intravenously 3 times a day" in the 4th to last paragraph was erroneously translated as "2 g of pyridoxal phospate intramuscular injection once a day; 1.5 g 3 times daily orally or intravenously; 10 ml of 1% solution glutamic acid". Applicants apologize for the error. Skochii et al. thus disclose the treatment of cerebral stroke in humans with a cocktail of antioxidants, including 1 ml of 5-10% oil solution of tocopherol acetate once daily intramuscularly; 3-5 ml of 5% solution of ascorbic acid once daily intramuscularly or intravenously; 2 g of pyridoxal phosphate once daily intramuscularly; 0.5 g of glutamic acid perorally or 10 ml of 1% solution intravenously 3 times a day. Hidden within this cocktail is 2 g of pyridoxal phosphate, once daily, intramuscularly. Dosing intramuscularly is not encompassed in the dosage regime recited in claim 1. Skochii et al. therefore do not provide a reasonable expectation of success that pyrixoxal-5'-phosphate, in the treatment regime claimed, would be successful in treating cerebral ischemia and ischemic stroke. Additionally, Skochii et al. does not teach or suggest all of the claim limitations.

Reasonable expectation of success

Skochii et al. do not teach that any of the individual components of the regimen taught in that reference would be successful in treating cerebral ischemia or ischemic stroke.

According to Skochii et al., it is the cocktail that produces the reduction in LPO concentration (See abstract). Skochii et al. describe the role of each of the different components administered to the 12 patients with low content of LPO products in the second subgroup (page 2, second paragraph). If each component has a role, then there is no reasonable expectation of success that the individual component of pyridoxal-5'-phosphate would treat cerebral ischemia and ischemic stroke. In addition, Skochii et al. teach an elaborate regimen, where certain compounds are given orally, others intravenously, and yet others intramuscularly. From the context of these teachings, these methods of administration would not be interchangable. Yet, Skochii et al. only teach intramuscular administration of pydidoxal-5'-phosphate. The presently claimed invention is an administration of pyridoxal-5'-phosphate by intravenous injection.

No teaching or suggestion of all the claim limitations

Skochii et al. do not teach administration of pyridoxal-5'-phosphate by intravenous injection. Rather, Skochii et al. disclose an elaborate cocktail of:

- 1 ml of once-daily tocopherol acetate solution intramuscularly,
- 3-5 mol of 5% ascorbic acid once daily intramuscularly or intravenously,
- 2 g of pyridoxal phosphate once daily intramuscularly, and
- 0.5 g of glutamic acid perorally or 10 ml of 1% solution intravenously 3 times a day.

Applicants respectfully assert that the Skochii et al. reference cannot be combined with any other reference to teach the instant claims since the cocktail in the Skochii et al. reference is so elaborate. Thus, the treatment regime in the Skochii et al. paper requires administration of substances intravenously, intramuscularly, and perorally. If it was clear to someone skilled in the art that all of these substances would have the same effect if given through one method of administration (for example, intravenously), Skochii et al. would have done so, since it would have simplified his treatment regime.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 USC § 103(a).

Summary

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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Date: August 4, 2006

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SUMMARY:

- A native speaker of Russian and Ukrainian with 15 years of broad experience as translator / interpreter.
- **180+** specialized dictionaries in my library.
- Translated *medical, legal, technical, business* material.
- Interpreting modes and settings: *Simultaneous/Consecutive/Summary (Conference/Court/Medical).*
- Marker for CTIC (Canadian equivalent of ATA) certification examinations; STIBC and ATIA admission examinations.

TRANSLATIONS USED BY:

Legal/Medical: US and Canadian Federal / State / Provincial / Local Government departments, ministries and agencies; courts and legal firms in the USA and Canada; medical equipment manufacturers (GE Medical Systems, Kimberly-Clark, etc.); Canadian / American hospitals, medical associations, medical and health-care institutions (Tufts-NEMC, MAMI, Tenet Healthcare, etc.); Health Care Insurance systems, providers and programs (Medi-Cal, Medicaid, Health Net, Healthy Families, etc.); professional clients and specialists.

Technical: Boeing, Ford, HP, Harris, Motorola, Nortel, Western Union; US AID; government agencies; various corporate and professional clients.

DOCUMENTS TRANSLATED:

Legal documents; reports; patent applications for new drugs; surveys, company policies, proposals, strategic planning and market studies, audits, project design and management; help files, service and repair manuals, technical specifications, descriptions and codes, instructions for medical equipment and devices; clinical studies, medical examinations and reports, various health-related documents.

EXPERIENCE:

1996-Present

60,000+ words per month of technical translations for companies in Vancouver, Chicago, Montreal, New York, Ottawa, Portland, San Francisco, Seattle and other cities throughout North America.

Interpreted at various seminars, conferences, meetings, discoveries, court hearings.

MOSAIC (Vancouver). Interpreter/translator.
Performed interpreting for the Ministries of Social Services, Attorney General, government workers, lawyers, health-care professionals, schools and School Boards.

Performed translations and typesetting for commercial clients of Mosaic.

1989-1996

30,000+ words per month of technical translations for companies in FSU countries.
80+ hours per month of free-lance interpreting for companies in Ukraine and FSU countries.

Interpreter/translator (a combination of both in-house and free-lance).
Performed consecutive and simultaneous interpreting from and into English, Russian and Ukrainian at business seminars, meetings, lectures in business, health care, banking, finance.

Translated legal documents, highly specialized texts in the above fields. Supervised translation projects.

EDUCATION: MA in English-Russian-Ukrainian translations. Kharkiv State University (Ukraine), 1993.

PROFESSIONAL AFFILIATIONS/DESIGNATIONS:

- **ATA Certified – Active Member (USA)** – ENG-RUS
- **CTIC Certified – Certified Translator (Canada)** – ENG-RUS, RUS-ENG, UKR-ENG
- **MITI – ITI Qualified Member (Great Britain)** – ENG-RUS
- **NAATI Accredited (Australia)** – ENG-RUS.

SAMPLES AND REFERENCES: Available upon request.

24-hr Fax•High-speed Internet•E-mail•FTP•PC MS Word, EPS/PDF files•TRADOS